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SUMMARY OF SAFETY AND EFFECTIVENESS

General Company Information

Name: Axya Medical, Inc.

Address: 100 Cummings Center
Suite 444C
Beverly, MA 01915

Telephone: (978) 232 - 9997
Fax: (978) 232 - 9998

General Device Information

Product Name: Bone Anchor System and Kit (BAK)

Classification: Accessory to an Endoscope – Class II

Predicate Devices

Axya Suturing and Ligating System (ASLS) [510(k) K980988]

Axya Suture Welding System and Kit (SWK) [510(k) K983108]

Description

The Axya Bone Anchor System consists of an electronic control module and a reusable welding activator with an integral connector cable. The Kit (BAK) consists of a suture welding sleeve, a suture manager and a suture guide packaged either alone or together with appropriate and currently approved bone anchors and USP polypropylene monofilament suture. The Kit is intended for use with the reusable system components in order to complete the suture welding process for the attachment of soft tissues to bone in surgical procedures where bone anchors or bone tunnels are required.

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Intended Use

The Bone Anchor System and Kit is indicated for securing soft tissue structures to bone in both open surgery and endoscopic (arthroscopic) surgical procedures. Examples of these procedures include:

Shoulder procedures	(e.g. Rotator cuff repair)
Knee procedures	(e.g. Patellar ligament / tendon avulsion repair)
Ankle procedures	(e.g. Achilles tendon reconstruction and repair)
Foot procedures	(e.g. Hallux valgus reconstruction)
Elbow procedures	(e.g. Biceps tendon reattachment)
Bladder neck suspension)	(female urinary incontinence due to urethral hypermobility)

Substantial Equivalence

This submission supports the position that the Axya Bone Anchor System and Kit (BAK) which includes USP size 2 polypropylene suture and a modified welding sleeve assembly is substantially equivalent to the original Bone Anchor System and Kit [501(k) K992405], and to the Axya Suturing and Ligating System (ASLS) [510(k) K980988], and the Axya Suture Welding System and Kit (SWK) [510(k) K983108]; and that it is appropriate for its intended application. Suture applicators and suture placement devices which may be used in both endoscopic or traditional open surgical procedures have been classified under 21 CFR 876.1500. These devices are indicated for the placement of sutures to close either traumatic or surgically produced wounds. The BAK is fabricated from materials with a substantial history of use in medical devices. Both the BAK and the predicate devices secure the suture loop with an ultrasonic weld.

The 510(k) Notice for the predicate ASLS system contains summaries of both *in vivo* and *in vitro* studies which were conducted to evaluate the safety, efficacy and appropriateness of the suture welding system. These data are applicable to the Bone Anchor System because the design and components of the welding mechanism are the same as those used in the BAK, ASLS and the SWK that were previously cleared for marketing. Data were presented which demonstrate that sutures placed by means of the suture welding process exhibit "knot strength" characteristics substantially above the USP requirements for the various USP suture materials tested. These tests confirm that the polypropylene monofilament sutures placed with the ultrasonic suture welding technology are equivalent in holding strength (efficacy) to sutures placed with conventional knotting techniques.

Data presented in the original Notice for the Bone Anchor System and Kit confirm that USP size 2 polypropylene monofilament sutures secured by a weld formed with the AxyaWeld Tips exceed the USP knot strength requirements. Data were presented that demonstrate that strength requirements are met regardless of the angle of applied tension between the suture and the bone anchor stem. Suture fatigue and elongation over the functional life were evaluated in bench-test models and the welded sutures have been found to meet the suggested criteria following cyclic testing.

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New data are presented that demonstrate that sutures welded in a fluid environment meet USP knot strength requirements. This supports the use of the system in closed endoscopic (arthroscopic) procedures. Additional data are presented that demonstrate that the system is suitable for use in bone tunneling procedures in addition to procedures in which soft tissue is attached to bone by means of bone anchors.

The safety of the suture delivery system was previously evaluated by placing both welded sutures and manually knotted sutures in the dorsal skin and in bowel tissue of New Zealand rabbits [510(k) K980988]. Positive (electrocautery contact) and negative (normal tissue) controls were used in the bowel study. In both animal models there was no histopathologic change seen at the suture implant sites where the suture was sealed with ultrasonic energy. The investigators concluded that there was no significant difference in safety of efficacy between the traditional method of suture placement and the technique which includes replacement of manual knot-tying with suture welding. The design of the AxyaWeld Sleeve also prevents the heated area of suture from coming into direct contact with tissues.

The ultrasonic energy source used to weld and secure the suture loop is the same generator used for the Automatic Suturing and Ligating System and that used for the Suture Welding System and Kit, and is similar to the energy source used in the UltraCision Harmonic Scalpel [510(k) K895252].

Because of design features of the BAK, no portion of the ultrasonic generator comes into contact with human tissues. Because of this, there is virtually no risk of causing a thermal injury to the patient. The suture material is heated and welded by friction and the weld is formed by melting and fusing the polymer. No "flux" or "welding rod" is employed and no new chemical entities are introduced or produced in the welding process.

The single-patient-use components of the Axya Bone Anchor System and Kit with a modified sleeve are provided sterile. The suture material and bone anchors are sterilized by the original manufacturer as dictated by the type of suture included with a given product configuration. The sterility processes, the manufacturing process, and the packaging process are validated by the manufacturer.

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed and pre-enactment devices have been used for the same types of clinical applications as the Axya Bone Anchor System and Kit. The materials from which the Axya device is fabricated have an established history of use in medical applications, and the specific materials used by Axya have been thoroughly tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2000

Mr. Howard L. Schrayer
Representing Axya Medical, Inc.
Axya Medical, Inc.
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

Re: K002435
Trade Name: AXYA Bone Anchor System and Kit
Regulatory Class: II
Product Code: GAW and MBI
Dated: August 8, 2000
Received: August 9, 2000

Dear Mr. Schrayer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K992405~~ K002435

Device Name: Axya, Bone Anchor System and Kit, (BAK)

Indications For Use:

The Bone Anchor System and Kit is indicated for approximating and securing soft tissue structures to bone in both traditional open surgery and endoscopic (arthroscopic)surgical procedures. Examples of these procedures include:

Shoulder procedures	(e.g. Rotator cuff repair)
Knee procedures	(e.g. Patellar ligament / tendon avulsion repair)
Ankle procedures	(e.g. Achilles tendon reconstruction and repair)
Foot procedures	(e.g. Hallux valgus reconstruction)
Elbow procedures	(e.g. Biceps tendon reattachment)
Bladder neck suspension	(female urinary incontinence due to urethral hypermobility)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002435

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)